As agreed between Agent for Applicant and the Examiner in a telephone conversation held on June 1, 2001, a Declaration under 37 CFR § 1.132 is not enclosed with this Amendment and Response but is forthcoming and will be considered as timely filed. This Declaration shows that the inventions were commonly owned at the time the invention in this application was made. In light of this Declaration and the above amendments and remarks, Applicant respectfully submits that the new claims are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 15, and 18-21 are rejected under 35 USC § 101 because the claimed invention is not supported by a specific asserted utility or well established utility. The Examiner states that the specification teaches general utility for the invention, not a specific utility. These claims have been canceled.

Furthermore, Applicant respectfully traverses this rejection. Applicant asserts that previously submitted arguments show a well-established utility and an asserted utility for the claimed invention. The specification teaches that the claimed gene products detected themselves in 5 of 6 normal prostate samples and in 3 of 3 prostate cancer specimens, thereby establishing that prostate tissue is the host tissue of the claimed gene products. Applicant further clarifies that the detection of the claimed gene products OUTSIDE their host prostate tissue is also diagnostically useful. Thus, presence of the claimed gene products outside normal host tissue serves as a diagnostic indicator that the host tissue is in a diseased state.

Although other tissue besides prostate tissue may normally express the claimed polynucleotides to some extent, it is the overexpression of the claimed gene products in tissue beyond this usual range that is of interest. The polynucleotides are of interest when they are overexpressed in a tissue or body compartment where their normal occurrence is very low or non-existent. Such overexpression indicates that a disease has altered the polynucleotides so that they escape from their host tissue (in this case prostate tissue) into other areas of the body. Thus, these polynucleotides are useful as markers for the detection of disease in prostate tissue.

The utility of gene products has been established in the art. The court has consistently stated that claim language must be read in light of prior art and teachings of the specification. The standard is that the "definiteness of the language must be analyzed...in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). The utility of gene products such as those claimed in the present invention is established in the art. Therefore, Applicant asserts that the examples and methods disclosed in the specification are useful for detecting, at the least, prostate diseases that may be detected using gene markers and related gene marker technology.

Applicant further reminds the Examiner that a protein or nucleic acid marker is useful not only for the direct detection of cancer in a biopsy sample but may also be useful in making a diagnosis or prognosis regarding the patient's disease status. Further, a protein or nucleic acid may not be present in high levels or at all in every tumor. For example, in the case of HER2-neu, only 1/3 of breast cancers overexpress this protein. Thus, in a breast cancer library, a very low level of HER2-neu will be present even though it is a very accurate breast cancer marker. Indeed, HER2-neu is used as a standard breast cancer marker.

Overexpression can be assessed by the well-known technique of immunohistochemistry using an antibody directed against the protein. For breast cancer patients with overexpression of HER-2-neu, treatment with Herceptin, a human-mouse chimeric antibody directed against the protein has therapeutic value. Also, if the gene which codes for HER-2-neu is amplified (multiple copies are present) as detected by the well known techniques of *in situ* hybridization, again the patient will likely respond to Herceptin treatment. However, if the patient does not exhibit an amplified gene or overexpression of the protein, treatment with Herceptin is unlikely to be of benefit.

Similarly, testing for estrogen receptor protein by immunohistochemistry is used as an indicator for treatment with anti-estrogens such as Tamoxifen. Only 2/3 of breast cancer patients express estrogen receptor in their tumors and thus benefit from Tamoxifen therapy. Based on the above, it is clear that the presence or absence of gene products which are expressed in the body is of diagnostic significance for cancer in a manner consistent with the methods and products claimed in new claims 22-53. Thus, the claimed polynucleotides of the present invention exhibit credible utility for several genres of tests well known in the art, whether direct or indirect in nature. Applicant respectfully submits that new claims 22-53 are now in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 15, and 18-21 are rejected under 35 USC § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant vigorously disagrees.

Claims 1-6, 11-12, 15, and 18-21 are rejected because the specification does not reasonably provide written description support for polynucleotides having varying percent identities.

The specification includes disclosure on making and using polynucleotide sequences and variants. The specification defines the term "identity" and provides methods and techniques for making and using polynucleotides of varying percent identities and for calculating percent identity (see pages 10-11). However, in an effort to clarify the nature of the polynucleotides of the instant application, Applicant has canceled claims 1-6, 11-12, 15, and 18-21. New claims 22-53 do not contain "identity", "fragment" or "complement" language. New claims 22-53 are further clarified by "degenerate codon equivalents" language. The degeneracy of the genetic code is a concept that is well-known to those skilled in the art and is even discussed in section 2144.09 of the February 2000 revision of the Manual for Patent Examining Procedure as "the fact that most amino acids are specified by more than one nucleotide sequence or codon." Applicant respectfully submits that the new claims are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 15, and 18-21 are rejected as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s) had possession of the claimed invention.

The Examiner states that the parent application U.S. Application Serial No. 08/938,383 filed September 19, 1997 does not disclose the specific fragments as set forth in the Amendment and therefore, the priority date awarded to the instant claimed is that of the instant application. Applicant respectfully disagrees that the sequences claimed in the instant application are therefore new matter.

Applicant indicated in the parent application that the sequences disclosed in the parent application may also contemplate fragments of the sequences disclosed. Thus, the specific fragments described in the parent application which are now referenced as SEQ ID NOS:1-5 and SEQ ID NOS:12-14 of the instant application are disclosed in the parent applications as set forth in Applicant's previous Amendment and are deserving of priority as set forth previously.

Applicant seeks to clarify. Position 4-269 of SEQ ID NO:2 are the same as nucleotides 11-276 of SEQ ID NO:4 of the parent application. Position 1-276 of SEQ ID NO:4 are the same as nucleotides 1-276 of SEQ ID NO:4 of the parent application. Position 1-276 of SEQ ID NO:5 are the same as nucleotides 1-276 of SEQ ID NO:4 of the parent application.

Although the Examiner has not yet granted priority to the parent application, the inventors were in possession of these sequences at the time of filing, as evidenced by the forthcoming Declaration referenced above.

Claims 1-3, 15, and 18-21 are rejected under 35 USC § 102(a) as being anticipated by Genbank Accession No. AA631976 or Genbank Accesion No. AA578209. These claims have been canceled. In view of the above amendments and remarks, Applicant respectfully submits that new claims 22-53 are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-3, 15, and 18-21 remain rejected under 35 USC § 102(b) as being anticipated by Genbank Accession No. Z39296, Genbank Accession No. R94063, Genbank Accession No. H72049, Genbank Accession No. H83957 or Genbank Accesion No. T83743. These claims have been canceled. In view of the above amendments and remarks, Applicant respectfully submits that new claims 22-53 are in a condition for allowance and requests that this rejection be withdrawn.

Claims 1-6, 11-12, 15, and 18 are provisionally rejected under 35 USC § 103(a) as being obvious over copending Application No. 09/065,383. These claims have been cancelled. In addition, Applicant directs the Examiner to the forthcoming Declaration under 37 CFR § 1.132 described above. This Declaration provides a showing that any invention disclosed but not claimed in the copending application was derived from the inventor(s) of this application and is thus not invention by "another".

Claims 1-6, 11-12, 15, and 18-21 are rejected under 35 USC § 103(a) as being unpatentable over any one of the following: Genbank Accession No. AA631976, Genbank Accesion No. AA578209, Genbank Accession No. Z39296, Genbank Accession No. R94063, Genbank Accession No. H72049, Genbank Accession No. H83957 Genbank Accesion No. T83743, Genbank Accession No. N74923, Genbank Accession No. AA280704, Genbank Accession No. Z39296 and Genbank Accession No. N80180 in view of Sambrook et al. These claims have been canceled. In view of the above amendments and remarks, Applicant respectfully submits that new claims 22-53 are in a condition for allowance and requests that this rejection be withdrawn.

CONCLUSION

In view of the aforementioned amendments and remarks, Applicant respectfully submits that the above-referenced application is now in a condition for allowance and Applicant respectfully requests that the Examiner withdraw all outstanding objections and rejections and passes the application to allowance.

Respectfully submitted,
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